IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Clark et al. Application No: 09/414,384 Confirmation No: 3236 Filed: October 7, 1999 Title: FLOW RESISTANCE MODULATED AEROSOLIZED ACTIVE AGENT DELIVERY	Group Art Unit: 3771 Examiner: Dixon, Annette Fredricka Attorney Docket No: 53235-US-CNT (NK.0037.00) October 28, 2009 San Francisco, California

APPEAL BRIEF

VIA U.S. MAIL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner:

In response to the Examiner's Final Rejection of May 1, 2009 and the Notice of Appeal filed on July 28, 2009, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby appeals to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection.

Certificate of Transmission

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By: Melanie Hitchcock — Date: October 28, 2009

Melanie Hitchcock

(1) *Real Party in Interest*

The real party in interest of the present application is Novartis AG (by way of assignment from Novartis Pharmaceuticals AG and from Nektar Therapeutics, which was formerly Inhale Therapeutic Systems, Inc.), having a place of business at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland.

(2) *Related Appeals and Interferences*

Appellant, Appellant's legal representative, and assignee are aware of no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

(3) *Status of Claims*

Claims 21-36 are presently pending in the case. Claims 21-36 have been finally rejected. The rejection of each of claims 21-36 is hereby appealed.

Claims 1-20 have been cancelled.

(4) *Status of Amendments*

A response after Final Office Action was filed on July 1, 2009. In an Advisory Action dated July 14, 2009, Examiner indicated that the response and arguments would be entered for the purposes of appeal. Therefore, the response is due entry.

All amendments made during prosecution have been entered.

(5) *Summary of the Claimed Subject Matter*

As recited in claim 21, a device (page 9 line 26 through page 10 line 15) for controlling the delivery of an aerosolized active agent (page 5 line 15 through page 7 line 14) to the lungs of a human patient comprises a valve (element 100, page 11 lines 13-15) that provides a high flow resistance of at least 0.4 (cm $H_2O)^{½}$ / SLM in the inhalation direction at the onset of the patient's inhalation and that subsequently opens during the inhalation to provide a lower flow resistance (page 10 line 24 through page 11 line 20). The lower flow resistance allows for a higher flow rate through the device.

As recited in claim 28, a device (page 9 line 26 through page 10 line 15) for controlling the delivery of an aerosolized active agent (page 5 line 15 through page 7 line 14) to the lungs of a human patient comprises a valve (element 100, page 11 lines 13-15) that provides a high flow resistance in the inhalation direction at the onset of the patient's inhalation. The flow resistance is selected to correspond to an inhalation flow rate of about 15 liters per minute or less. The valve subsequently opens during the inhalation to provide a lower flow resistance which is selected to correspond to a higher flow rate (page 10 line 24 through page 11 line 20).

As recited in claim 32, a device (page 9 line 26 through page 10 line 15) for controlling the delivery of an aerosolized active agent (page 5 line 15 through page 7 line 14) to the lungs of a human patient comprises a valve (element 100, page 11 lines 13-15) that is adapted to provide a first flow resistance in the inhalation direction at the onset of the patient's inhalation and that subsequently opens during the inhalation to provide a second flow resistance (page 10 line 24 through page 11 line 20). The second flow resistance is less than the first flow resistance, wherein the second flow resistance allows for a higher flow rate.

(6) *Grounds of Rejection to be Reviewed on Appeal*

Appellant requests review of the Examiner's following grounds of rejection:

Claims 21, 24, 28, 32, 34 and 36 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,479,920 to Piper et al (hereinafter Piper et al).

Claims 22, 23, 26, 27, 30, 31 and 33 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Piper et al.

Claims 25, 29 and 35 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Piper et al in view of U.S. Patent 4,227,522 to Carris (hereinafter Carris).

(7) *Argument*

Appellant believes each of claims 21-36 is improperly rejected and is therefore allowable for the following reasons:

The rejections under §102(b) are improper

The Examiner's rejection of claims 21, 24, 28, 32, 34 and 36 under 35 USC §102(b) as being anticipated by Piper et al is improper and should be reversed.

Independent claim 21

Piper et al does not anticipate independent claim 21, for example. For a rejection under 35 USC §102 to be proper, the reference relied upon must disclose each and every element of the claimed invention. Non-disclosure of a single element, feature or limitation of the claim negates anticipation.

Claim 21 is to a device for controlling the delivery of an aerosolized active agent comprising, inter alia, a valve that provides a high flow resistance of at least 0.4 (cm $H_2O)^{½}$ / SLM in the inhalation direction at the onset of the patient's inhalation. This positively recited feature is not disclosed by Piper et al, as will be described. Since Piper et al does not disclose each and every feature set forth in claim 21, it does not anticipate the claim. Therefore, reversal of the rejection of claim 21 is requested.

Piper et al does not disclose a valve that provides a high flow resistance of at least 0.4 (cm $H_2O)^{½}$ / SLM in the inhalation direction at the onset of the patient's inhalation. Instead, Piper et al discloses a one-way valve (element 24) that provides a high flow resistance only in the exhalation direction (see column 4 lines 33-35). There is no high flow resistance in the inhalation direction in the Piper et al device as the valve (24) opens immediately upon inhalation. Therefore, Piper et al does not disclose the valve as claimed in claim 21.

The Examiner's comments in the Final Office Action do not serve to establish Piper et al as an anticipatory reference. The Examiner posits that valve 24 of Piper et al satisfies the claim limitation because there is pressure built up within the system during a patient's exhalation. The Examiner's contention is incorrect for several reasons. First, Appellant's recitation in claim 21 relates to a structural feature of the claimed valve. That is, Appellant recites a high flow resistance in an inhalation direction. In contrast, valve 24 of Piper et al has a high flow resistance only in the exhalation direction. As recited in column 4 lines 22-24 of Piper: "A one-way (unidirectional) inhalation valve **24**, which is a conventional flapper valve or the like wherein the valve opens to permit flow in one direction [*i.e.* in the inhalation direction] but closes to prevent flow in the other direction [*i.e.* in the exhalation direction], ..." [bracketed comments added]. Thus, the valve 24 of Piper et al is not a valve that includes the positively set forth structural feature of claim 21 where it is required that the valve provide a high flow resistance of at least 0.4 (cm $H_2O)^{½}$ / SLM in the inhalation direction. Therefore, the Examiner's comments are not correct for this first reason.

Additionally, the Examiner position is incorrect because the Examiner ignores positively recited claim language in claim 21. Claim 21 recites that the valve provides a high flow resistance of at least 0.4 (cm $H_2O)^{½}$ / SLM in the inhalation direction. As discussed above, the Examiner relies on the presence of exhalation pressure to satisfy this limitation. However, there is no disclosure or suggestion in Piper et al that the "flow resistance" provided by the valve changes because of any exhalation pressure buildup. To the contrary, Piper et al specifically states that "when the patient inhales, valve **24** opens and pressure in the breathing circuit drops to a level below atmospheric pressure." Thus, the Examiner appears to be confusing "flow resistance" with "flow." Whether or not there is instantaneous flow through the valve 24 in Piper et al at the onset of inhalation has no relevance to what the flow resistance is at the onset of inhalation. By way of example, consider a simple straight pipe. The flow resistance of the pipe is constant and does not change based on relative pressures on opposite ends of the pipe. While flow is dependent on the pressures, the flow resistance is not. Thus, the backside pressure referred to by the Examiner may alter flow through the valve 24 of Piper et al, but it does not alter the flow resistance.

Moreover, assuming *in arguendo* that the Examiner is correct and there is a slight increase in flow resistance through the valve 24 because of backside exhalation pressure, the Examiner has made no accounting for there being a flow resistance that is as high as that claimed in claim 21, i.e. at least 0.4 (cm $H_2O)^{½}$ / SLM. This extremely high flow resistance would not be achieved by the situation described by the Examiner. Thus, for these additional reasons, the Examiner's position taken in the Final Office Action is improper.

For at least these reasons, Appellant requests reversal of the rejection of claim 21 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claim 24 which depends from claim 21 and is not anticipated by Piper et al for at least the same reasons as claim 21.

Independent claim 28

Piper et al also does not anticipate independent claim 28. Claim 28 is to a device comprising, *inter alia*, a valve that provides a high flow resistance in the inhalation direction at the onset of the patient's inhalation and which corresponds to a flow rate of about 15 liters per minute or less and that subsequently opens during the inhalation to provide a lower flow resistance. Piper et al does not disclose a valve that provides a high flow resistance in the inhalation direction at the onset of inhalation. Instead, as discussed above, Piper et al's valve (24) opens at the onset of inhalation and provides little, if any, flow resistance in the inhalation direction. Furthermore, Piper et al's valve (24) does not exhibit a change in flow resistance during an inhalation, as required by claim 28. Thus, Piper et al does not anticipate claim 28.

For at least these reasons, Appellant requests reversal of the rejection of claim 28 under 35 U.S.C. §102(b).

Independent claim 32

In addition, Piper et al does not anticipate independent claim 32. Claim 32 is to a device comprising, *inter alia*, a valve that is adapted to provide a first flow resistance in the inhalation direction at the onset of the patient's inhalation and that subsequently opens to provide a second flow resistance less than the first flow resistance. Piper et al does not disclose a valve that has a first flow resistance in the inhalation direction at the onset of inhalation that subsequently changes, as discussed above. Thus, Piper et al does not anticipate claim 32.

For at least these reasons, Appellant requests reversal of the rejection of claim 32 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claims 34 and 36 which depend from claim 32 and is not anticipated by Piper et al for at least the same reasons as claim 32.

The rejections under §103(a) based on Piper et al alone are improper

The Examiner's rejection of claims 22, 23, 26, 27, 30, 31 and 33 under 35 USC §103(a) as being unpatentable over Piper et al is not proper and should be reversed.

Claims 22 and 23 depend from claim 21; claims 26, 27, 30 and 31 depend from claim 28; and claim 33 depends from claim 32. Piper et al does not render independent claims 21, 28 and 32 unpatentable as discussed above. Thus, claims 22, 23, 26, 27, 30, 31 and 33 are allowable over Piper et al for at least the same reason as the claims from which they depend.

In addition, it would not have been obvious to one having ordinary skill in the art to modify Piper et al in a manner that would result in the invention set forth in the claims. There is no reason why one of ordinary skill would have been motivated to provide a valve that provides a high flow resistance at the onset of inhalation and that subsequently opens to provide a lower flow resistance. Such a modification is antithetical to the teachings of Piper et al where it is desired to allow for unrestricted inhalation flow.

For at least these reasons, claims 22, 23, 26, 27, 30, 31 and 33 are not properly rejectable under 35 USC §103(a) as being unpatentable over Piper et al. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the proposed modification could be applied with a reasonable likelihood of success to Piper et al. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined teachings in a manner that would result in the invention of claims 22, 23, 26, 27, 30, 31 and 33, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claims 22, 23, 26, 27, 30, 31 and 33 are allowable over the references cited.

Appellant requests reversal of the rejection of claims 22, 23, 26, 27, 30, 31 and 33 under 35 U.S.C. §103(a).

The rejections under §103(a) based on Piper et al and Carris are improper

The Examiner's rejection of claims 25, 29 and 35 under 35 USC §103(a) as being unpatentable over Piper et al and Carris is not proper and should be reversed.

Claims 25 and 29 depend from claim 21, and claim 35 depends from claim 32. Piper et al does not render independent claims 21 and 32 unpatentable as discussed above. Carris is not relied upon to make up for the deficiencies of Piper et al, nor does it. Since claims 21 and 32 are not rendered unpatentable by the combination of Piper et al and Carris, claims 25, 25 and 35 which depend therefrom are also not rendered unpatentable by the references.

Appellant requests reversal of the rejection of claims 25, 29 and 35 under 35 U.S.C. §103(a).

Conclusion

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: October 28, 2009

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(8) Claims Appendix

21. A device for controlling the delivery of an aerosolized active agent to the lungs of a human patient, said device comprising a valve that provides a high flow resistance of at least 0.4 (cm $H_2O)^{½}$ / SLM in the inhalation direction at the onset of the patient's inhalation and that subsequently opens during the inhalation to provide a lower flow resistance, wherein the lower flow resistance allows for a higher flow rate through the device.

22. A device according to claim 21 wherein the high flow resistance is a resistance of between 0.4 and 2 (cm $H_2O)^{½}$ / SLM.

23. The device of claim 21 wherein the lower flow resistance is a resistance between 0 and 0.3 (cm $H_2O)^{½}$ / SLM.

24. The device of claim 21 wherein the high flow resistance corresponds to a flow rate of 15 liters per minute or less.

25. The device of claim 21 wherein the lower flow resistance corresponds to a flow rate of 15-80 liters per minute.

26. The device of claim 21 wherein the high flow resistance is provided for an initial time period of less than 10 seconds.

27. The device of claim 21 wherein the high flow resistance is provided for an initial time period of less than 5 seconds.

28. A device for controlling the delivery of an aerosolized active agent to the lungs of a human patient, said device comprising a valve that provides a high flow resistance in the inhalation direction at the onset of the patient's inhalation and which corresponds to a flow rate of about 15 liters per minute or less and that subsequently opens during the inhalation to provide a lower flow resistance which corresponds to a higher flow rate.

29. The device of claim 28 wherein the lower flow resistance corresponds to a flow rate of between about 15 and 80 liters per minute.

30. The device of claim 28 wherein the high flow resistance is a resistance of between about 0.4 and 2 (cm $H_2O)^{½}$ / SLM.

31. The device of claim 28 wherein the high flow resistance is provided for an initial time period of less than about 10 seconds.

32. A device for controlling the delivery of an aerosolized active agent to the lungs of a human patient, said device comprising a valve that is adapted to provide a first flow resistance in the inhalation direction at the onset of the patient's inhalation and that subsequently opens during the inhalation to provide a second flow resistance, the second flow resistance being less than the first flow resistance, wherein the second flow resistance allows for a higher flow rate.

33. The device of claim 32 wherein the first flow rate is provided for an initial time period of less than about 10 seconds.

34. The device of claim 32 wherein the first flow rate is less than about 15 liters per minute.

35. The device of claim 34 wherein the second flow rate is between about 15 and 80 liters per minute.

36. The device of claim 32 wherein the first flow resistance provides a first flow rate and wherein the second flow resistance provides a second flow rate.

(9) Evidence Appendix

none

(10) Related Proceedings Appendix

none